

**Program
Section Track****Exhibit B****Analysis and Pharmaceutical Quality (APQ)****Recent Advances in HPLC and Related Chromatographic Procedures – Application in Small vs. Large Molecules; Cross-fertilization Between Bioanalytical and Pharmaceutical Analysis Disciplines**

Sunday, November 11

8:30 am – 4:00 pm

SHORT COURSE

ACPE #073-999-07-503-L04

High Performance Liquid Chromatographic techniques and technologies have dominated small molecule quantitative and qualitative analyses for more than a quarter of a century. Many of these techniques plus other types of chromatography have been utilized to explore, characterize, qualify, quantify and describe the chemical, biological and physical interactions of such biologically based compounds as proteins, polypeptides, nucleic acids, nucleotides, nucleosides dissolved in various biological matrices. Because small and large molecules possess different attributes which are relied upon to provide their particular efficacies, liquid chromatographic methods have been developed and validated to accommodate their differences in chemical, biological and physical behaviors. For instance, while it is sufficient for an HPLC potency assay and purity determination to describe the quality of many small molecules in aqueous, buffer, organic solvent solutions, large biomolecules such as proteins must be tested differently, taking care not to disrupt not only the primary amino acid structure, but secondary and tertiary confirmations so that denaturation is avoided and the molecule will retain its chemical composition, shape, size and volume. The need to characterize a rather fragile, large, three-dimensional macromolecule necessitates that a profile of test results be obtained from a variety of test methods. Some of these bioanalytical techniques may have use in the world of small molecule evaluation, though never utilized, while some small-molecule techniques could more easily work for biomolecules than some of the more time consuming and complex techniques developed over the past ten or so years.

This course is designed to give an overview of techniques frequently used by analytical applications as well as bioanalytical applications, examining each component of analysis and then drawing suitable comparisons. The purpose of such an exercise is to reveal to analysts and bioanalysts, possible practices which would facilitate a cross-fertilization of information and enhance efficiency, accuracy, precision and execution time required to carry-out the methodologies.

MODERATOR

Prasad N. Tata, Ph.D., F.C.P.
Mallinckrodt, Inc.

Do We Need to Use the Same Methodology?

Prasad Tata, Ph.D., F.C.P.
Mallinckrodt, Inc.

**Sample Preparation Techniques Small vs. Large Molecule in Pharmaceutical Characterization and Bioanalysis;
Clean-up and/or Preparation Prior to Chromatographic Analysis**

Speaker to be announced

Column Selection and Separation Methodologies – There Is Room Beyond Reverse Phase HPLC

Xiande (Andy) Wang, Ph.D.
Synomics Pharma

Role of Various Chromatographic Methods in the Characterization of Bulk Drugs and Dosage Forms

Reb Russell, Ph.D.
Bristol-Myers Squibb Company

Detection Techniques Available for Qualitative and Quantitative Assays – Small vs. Large Molecules

David C. Muddiman, Ph.D.

North Carolina State University

Chiral Separations – Large, Small Does Size Matter?

Fakhreddin (Mo) Jamal, Ph.D.

University of Alberta

Application of Various Analytical Techniques in the Clinical Drug Development Studies, Large Molecule vs. Small Molecule, Cross Usage of Same Analytical Method for Pharmaceutical Analysis and Bioanalytical Work, Is It Possible?

Krishna Devarakonda, Ph.D.

Kakatiya University

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